

**NOT RECOMMENDED FOR FULL-TEXT PUBLICATION**

File Name: 14a0162n.06

Case No. 13-3729

**UNITED STATES COURT OF APPEALS  
FOR THE SIXTH CIRCUIT**

**FILED**  
Feb 27, 2014  
DEBORAH S. HUNT, Clerk

MARY K. WOODFILL,	)	
	)	
Plaintiff-Appellant,	)	
	)	
v.	)	ON APPEAL FROM THE UNITED
	)	STATES DISTRICT COURT FOR
	)	THE NORTHERN DISTRICT OF
SECRETARY OF HEALTH AND HUMAN	)	OHIO
SERVICES,	)	
	)	
Defendant-Appellee.	)	
	)	

BEFORE: DAUGHTREY, SUTTON and DONALD, Circuit Judges.

SUTTON, Circuit Judge. Mary Woodfill sought Medicare coverage for an implantable infusion pump. Because Medicare prohibits coverage for this kind of device in this setting, the Secretary of Health and Human Services denied coverage. The district court upheld that determination, and we affirm.

Woodfill has “severe spinal degenerative disease,” and has lived with “chronic low back pain . . . for over twenty years.” R.54 at 5. She currently uses “high dosages of multiple pain medications” to manage the pain. *Id.* On top of that, her doctors implanted a spinal cord stimulator in the mid-1990s, which provided some relief. *Id.* To provide further relief, Woodfill’s doctors recommended an implantable infusion pump, which would deliver pain

medication directly to the spinal cord and thus offered the prospect of additional relief. R.54 at 13.

Woodfill’s health insurance provider, Humana, denied the request to cover the costs of the pump and the procedure for inserting it. R.55 at 166–67, 189. Woodfill appealed the decision—first to Humana for reconsideration, then to an outside reviewer and then to the Department of Health and Human Services. R.55 at 159–60. An administrative law judge, Catherine Fuller, upheld the denial of benefits. R.54 at 26–28. The Medicare Appeals Council adopted the administrative law judge’s decision. R.54 at 4–8. And, as permitted by Congress, Woodfill filed this action challenging that decision. *See* 42 U.S.C. § 405(g); R.1. The district court upheld the agency’s determination, holding that substantial evidence supports it.

Woodfill receives Medicare benefits through the Medicare Advantage Program (also known as Medicare Part C). The program allows individuals to receive health benefits from private health insurance companies that contract with the federal government to provide them. 42 U.S.C. § 1395w-21. The individual receives any benefits that traditional Medicare programs cover along with any other benefits she opts to pay for or the private company opts to provide. 42 U.S.C. § 1395w-22.

Medicare covers “reasonable and necessary” services, and the Secretary may issue national coverage determinations that describe the services satisfying these requirements. 42 U.S.C. §§ 1395y(a), 1395ff(f)(1)(B). The process works as follows: After receiving a request for a determination or deciding to issue a determination on her own, the Secretary may issue a proposed determination, solicit public comment and, if appropriate, issue a final determination. *See* Notice, Revised Process for Making National Coverage Determinations, 78 Fed. Reg. 48,164-01 (Aug. 7, 2013). When handling requests for coverage, insurers like Humana as well

as all agency actors in the administrative appeals process must adhere to those determinations. 42 C.F.R. § 405.1060(a).

The Secretary has issued a national coverage determination with respect to infusion pumps. It permits Medicare coverage for an “implantable infusion pump” when, among other things, it is “used to administer opioid drugs . . . for treatment of severe chronic intractable pain.” National Coverage Determination Manual Ch. 1 Pt. 4, 142, 280.14(B)(2)(c). An individual must show that she expects to live at least three months, that she “would not respond adequately to noninvasive methods of pain control,” and that she responded well to a temporary trial that approximates the effects of the pump. *Id.* The determination adds, however, that the pump “is contraindicated”—which is to say, not recommended—for patients with “other implanted programmable devices since crosstalk between the devices may inadvertently change the prescription.” *Id.* at 142–43, 280.14(B)(2)(e). “Crosstalk” means unprompted communications between devices, such as a signal from a spinal cord stimulator that changes the pain medication dosage setting on an implantable infusion pump.

In view of the “is contraindicated” limitation, the Secretary has categorically excluded implantable pumps from coverage if a patient already has one implanted electronic device. Woodfill has not challenged that interpretation. Before the district court and before this court, Woodfill has argued only that the rationale behind the bar—the risk of crosstalk—does not apply to her case. R.62. We will proceed under the Secretary’s reading of the determination, as Woodfill has offered no other.

In view of the Secretary’s unchallenged interpretation of the regulation, she permissibly denied coverage for Woodfill’s pump. Medicare covers implantable infusion pumps to administer pain medication *except when* an otherwise eligible patient already has another

implanted electronic device. Woodfill already has another implanted electronic device: the spinal cord stimulator. Medicare thus does not cover her pump.

Woodfill’s main argument—that the requested pump does not present any risk of crosstalk—speaks to the wisdom of the determination’s categorical bar, not to its existence. Woodfill argues that many patients like her need two implanted electronic devices to control pain and physicians often recommend two devices. *See, e.g.*, R.54 at 10. And she points to the administrative law judge’s finding that the pump she wants “was engineered not to crosstalk with other devices,” limiting the risk of “crosstalk between the spinal cord stimulator and the proposed implantable pump.” R.54 at 40. These facts may well suggest that the determination’s categorical bar deserves further consideration. But this action is not the route for reconsidering the bar. Instead, Woodfill may wish to file a complaint with the Department of Health and Human Services. 42 U.S.C. § 1395ff(f)(1)(A). For present purposes, the Secretary did not abuse her discretion in applying the categorical bar here.

For these reasons, we affirm.